K081906

NOV 14 2008

510(K) Summary: PROTEX® CT Occipito-Cervico-Thoracic Spinal System

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
(610) 415-9000

Contact: Kelly J. Baker, Ph.D
Director, Clinical Affairs & Regulatory

Device Name: PROTEX® CT Occipito-Cervico-Thoracic Spinal System

Classification: Per 21 CFR as follows:
§888.3050 Spinal Interlaminal Fixation Orthosis
Product Code KWP.
Regulatory Class II, Panel Code 87.

Predicate(s): Globus Medical PROTEX® CT Cervicothoracic Spinal System
K050391, SE date February 15, 2005
Product Code KWP and MNI
Regulatory Class II, Panel Code 87.

Device Description:
The PROTEX™ CT Occipito-Cervico-Thoracic Spinal System consists of 3.2mm and 3.7mm rods, polyaxial screws, hooks, locking caps, t-connectors, lateral connectors, parallel connectors, and occipital clamps. The implants are composed of titanium alloy (per ASTM F136, F1472, or F1295), or stainless steel (per ASTM F138).

Due to the risk of galvanic corrosion following implantation, titanium alloy implants should not be connected to stainless steel implants.

Intended Use:
The PROTEX® CT Occipito-Cervico-Thoracic Spinal System is intended to be used in skeletally mature patients as an adjunct to fusion using autograft or allograft, for stabilization of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) for the following conditions: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, atlanto/axial fracture with instability, occipitocervical dislocation, revision of previous cervical spine surgery, and tumors.

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine. Occipital bone screws are limited to occipital fixation; they are not intended for fixation of the posterior cervical spine. The 3.2mm rod

implants are for use in the cervical and upper thoracic spine and are not intended for occipital fixation.

The PROTEX® CT Occipito-Cervico-Thoracic Spinal System 3.7mm rods can also be linked to rod systems ranging in diameter from 3.7mm to 6.5mm, including the PROTEX® or REVERE® System, using corresponding parallel connectors.

Basis of Substantial Equivalence:
The PROTEX® CT additional implants are similar to the predicate PROTEX® CT implants with respect to technical characteristics, performance, and intended use. Mechanical testing in accordance with the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004 is presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Globus Medical Inc.
% Kelly J. Baker, Ph.D.
Director, Clinical Affairs & Regulatory
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K081906
Trade/Device Name: PROTEX® CT Occipito-Cervico-Thoracic Spinal System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis.
Regulatory Class: II
Product Code: KWP
Dated: October 14, 2008
Received: October 15, 2008

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K081906

Device Name: PROTEX® CT Occipito-Cervico-Thoracic Spinal System

INDICATIONS:

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Prescription Use __X____ OR Over-The-Counter Use____
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081906